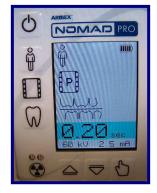
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NOMAD Pro™ Handheld X-ray System (Project 08-19) (10/09)

The NOMAD Pro[™] Handheld X-ray System is a "second-generation" portable, handheld, battery-operated dental x-ray unit manufactured by AribexTM. It comes with a Charging Cradle (110/120V or 220/240V) and two rechargeable Handsets (handles) which contain 22.2V lithium polymer batteries. The batteries were a separate feature on the initial NOMAD™ unit and were inserted into the permanently attached handle of that unit. The NOMAD Pro™ differs in that the batteries are permanently installed into the removable handle (Handset). The NOMAD Pro[™] is approximately 39% lighter than the original NOMAD™. Touchpad controls have been redesigned and moved from the previous rear position on the NOMAD™ unit to the top surface of the NOMAD Pro™. Factory default exposure settings based on patient size (adult or child). receptor type (film, phosphor plate or direct sensor) and tooth group (anterior, posterior, or bitewing) designed to simplify appropriate radiograph exposure level selection are now available and accessed by icon touchpad controls. A larger color LCD screen illustrates exposure settings and battery life information. An added "X-ray Lock/Unlock" feature can be activated to prevent unauthorized use of the unit. Table 1 compares "Specifications" of the NOMAD Pro™ with those of the NOMAD™ unit. Like the original NOMAD™ unit, the NOMAD Pro™ uses direct current, operates at a fixed 60 kVp, has a 0.4 mm focal spot and a 20 cm source-to-skin distance. Fixed milliamperage (mA) has been increased from 2.3 mA on the NOMAD™ to 2.5 mA on the NOMAD Pro™. Exposure time range has been increased on the high end by 0.01 seconds. The NOMAD Pro[™] has a one-year warranty.





NOMAD Pro™ Touchpad Controls and LCD Screen

Table 1: Specification Comparison NOMAD™ and NOMAD Pro™

| UNIT | NOMAD™ | NOMAD Pro™ |
|-------------------------|--------------------------------|----------------------------------|
| Battery | NiCd, 14.4V, 2 Ahr | Lithium Polymer, 22.2V, 1.25 Ahr |
| Anode voltage | 60 kV true DC | 60 kV true DC |
| Anode current | 2.3 mA | 2.5 mA |
| Exposure time range | 0.01 - 0.99 sec | 0.01 – 1.00 sec |
| Focal spot | 0.4 mm | 0.4 mm |
| Inherent filtration | > 1.5mm Al | > 1.5mm Al |
| Source to skin distance | 20 cm | 20 cm |
| X-ray field | 60 mm round | 60 mm round |
| Maximum duty cycle | 1:60 | 1:60 |
| Total weight | 4 Kg (8.9 lbs) | 2.45 kg (5.4 lbs) |
| Approximate dimensions | W 5 3/8" x L 13.0" x H 11 3/8" | W 5 1/4" x L 10 1/2" x H 9 3/4" |

Manufacturer:

Aribex, Inc. 744 South, 400 East Orem, UT 84097 (866) 340-5522 (801) 226-5522 (801) 434-7233 FAX www.aribex.com

Distributor:

Aseptico, Inc. 8333 216th St. S.E. Woodinville, WA 98072 (800) 426-5913 (425) 487-3157 (360) 668-8722 FAX www.aseptico.com

Suggested Retail Price:

\$7,495.00 Aribex NOMAD Pro™ x-ray unit (item # ARU-07LC) includes:

- Handheld x-ray unit
- 2 rechargeable battery Handsets/handles
- Charging cradle
- AC/DC power supply adapter

| \$7,960.00 | Aribex NOMAD Pro™ x-ray unit in standard case (ARU-07) |
|------------|--|
| \$9,270.00 | Aribex NOMAD Pro [™] x-ray unit in large hard-shell case (ARU-07CL) |
| \$320.00 | Rechargeable battery Handsets/handles (AP-0025) |

\$114.00 Charging cradle (AP-0035) \$65.00 AC/DC power supply adapter

(Item order numbers and prices are from Aseptico, Inc.)

Government Price:

| Government Price: | | |
|-------------------|---|--|
| \$6,243.34 | Aribex NOMAD Pro ™ x-ray unit (item numbers and contents as listed above) | |
| \$6,630.00 | Aribex NOMAD Pro™ x-ray unit in standard case | |
| \$6,953.10 | Aribex NOMAD Pro™ x-ray unit in large hard-shell case | |
| \$288.00 | Rechargeable battery Handset/handle | |
| \$102.60 | Charging cradle | |
| \$58.50 | AC/DC power supply adapter | |

(Item order numbers and prices are from Aseptico, Inc.)

ADVANTAGES:

- + Portable, handheld, battery-operated
- + User-friendly touchpad controls and LCD screen
- + Excellent Operator Training compact disc
- + Reduced weight compared to original model
- + Meets applicable radiation safety standards
- + Personal dosimetry not required
- + Easy to set up, learn, and use
- + Two detachable Handsets/rechargeable batteries and charger
- + Battery provides 118 or more exposures per charge
- + Two choices of ruggedized carrying/shipping cases
- + Added "X-ray Lock/Unlock" function
- + Useful for forensic identifications, field operations, humanitarian missions

DISADVANTAGES:

- Multiple, successive exposures with fully-extended arms may cause arm fatigue
- Backscatter shield may not always provide complete shielding
- Manufacturer pre-set exposure times may need adjusting
- Battery life may be less than original unit

SUMMARY AND CONCLUSIONS: The Aribex NOMAD Pro[™] battery-operated Handheld X-ray System is the lightest and most portable x-ray unit evaluated by DECS. Radiation safety test results from the USAF Radiation Dosimetry Laboratory and DECS demonstrated that the NOMAD Pro[™] meets radiation safety standards and does not require personal dosimetry (Click here for the updated NOMAD Pro Radiation Safety Fact Sheet and Guidelines For Use). Aribex provides an Operator Training compact disc (CD) with every NOMAD Pro™. Considering the outstanding quality of this instructional material, DECS highly encourages the use of this CD and the accompanying exam/certificate to document training within our Air Force clinics. Clinical evaluators were impressed with how easy the NOMAD Pro[™] was to set up and operate. They put it to immediate use in a range of clinical applications including examinations. endodontic, implant, and pediatric operating room procedures. Evaluators stated radiographic quality was acceptable, although manufacturer-recommended pre-set exposure times required some adjusting. They noted that with some patient-positions the backscatter shield could not provide the operator with maximum shielding. Upgrades on the NOMAD Pro™ including reduced weight, better positioned touchpad controls/LCD screen, a redesigned "one-handed use" trigger switch and an added X-ray Lock/Unlock function all combined to significantly improve ease of use and security to prevent unintended exposures. Clinical users were very impressed with the NOMAD Pro™ and cited its significant potential for use in routine clinical dental exams/procedures when indicated, forensic dentistry, on humanitarian missions, and in deployed locations. All evaluators rated the NOMAD Pro™ excellent or outstanding and recommended it for purchase. The Aribex **NOMAD Pro™** is rated **Outstanding** for use in US Air Force dental facilities.

NOMAD Pro™ RADIATION TEST RESULTS -- FACT SHEET

1. Applicable Dental Radiation Safety Standards:

- a. Whole-body Deep-dose Equivalent to the Operator: 5,000 mrem/yr.
 - *This is the **key** standard used in assessing occupational dental radiation safety. Personal dosimetry is required when the operator is expected to receive 10% or more of the Whole-body Deep-dose (500 mrem/yr).
- b. Shallow-dose Equivalent to the Hand due to Scatter and Leakage Radiation: 50,000 mrem/yr.
 - *Personal dosimetry is required when the operator is expected to get 10% of the Shallow-dose Equivalent (5,000 mrem/yr).
- c. Total Effective Dose Equivalent to the Public: 100 mrem/yr and 2 mrem in any one hour.
- 2. Summary of AFIOH NOMAD test results:

a. Whole-Body Deep-Dose Equivalent to the Operator.

Assuming 15,000 exposures/year the predicted annual Whole-body Deep-dose equivalent to the operator was estimated, from test results, to be 270 mrem/year. This is well below the limit of 5,000 mrem/year and the requirement for mandatory personal dosimetry of 500 mrem/yr.

b. Shallow-dose Equivalent to the Hand due to Scatter and Leakage Radiation:

Assuming 15,000 exposures/year, the predicted Annual Shallow-dose Equivalent to the operator's extremity was estimated, from test results, to be 1,277 mrem/year. This is well below the limit of 50,000 mrem/year and the requirement for mandatory personal dosimetry of 5,000 mrem/yr.

c. Total Effective Dose Equivalent (TEDE) to the Public:

- Assuming 15,000 exposures/year, the annual TEDE to the public was estimated, from test results, to be 1260 mrem/yr for an individual standing 4.0' away in the direct path of the beam on the opposite side of the patient, 30.0 mrem for an individual standing 1'10" to the left or right of the patient, and 94.5 mrem for an individual standing 6' away in the path of the beam.
- The estimated annual TEDE of 30.0 mrem to a member of the general public standing 1'10" to the left or right of the cone and 94.5 mrem at a distance of 6' fall within the annual dose limit for the public of 100.0 mrem. An individual standing 4.0' away in the path of the x-ray beam would appear to dramatically exceed the limit. This is because the calculation used includes data from a background TLD. Raw dose from the TLD located 4.0' away from the NOMAD Pro™ was recorded at 0.9 mrem (dose which can be attributed to the NOMAD Pro™), while the background TLD (approximately 20' away) recorded a raw dose of 5.1 mrem (not attributed to the NOMAD Pro™). The formula to determine the TEDE to an individual standing in this location takes into consideration both values. Since the background value is much higher, the resultant 1,260 mrem/yr value is high due to this high background value which was specific to the room used within the testing environment and not directly related to the radiation produced by the NOMAD Pro™. Members of the general public would not be expected to be in these locations for 15,000 exposures.
- Assuming a maximum duty cycle of 60 exposures per hour, the estimated TEDE to the public in any one hour was calculated to be 5.04 mrem for an individual standing 4.0' away on the opposite side of the phantom, 0.12 mrem for an individual standing 1'10" to the left or right of the phantom, and 0.76 mrem for an individual standing 6' away to the side. Again the high hourly value at the 4.0' location is due to the radiation recorded from the background TLD and is not directly attributed to the NOMAD Pro™. The other two locations meet the "2 mrem in any one hour" requirement.

3. Summary of DECS Simulated-Clinical-Operator NOMAD Test Results:

- Three-hundred periapical/bitewing exposures were made through a human skull with dosimeters at the left clavicle, right hip, left little finger, and right index finger of the operator.
- No radiation was detected by the dosimeters on the left clavicle and right hip, so safety standards for Whole-body Deep-dose Equivalent were met.
- No radiation was detected by the dosimeters on right index finger and left little finger dosimeters, thus safety standards for Shallow-dose Equivalent to the Extremity were met.

4. Comment on backscatter shield protection:

With some patient positions, it may not always be possible to position the NOMAD Pro™ and backscatter shield to fully/ideally shield the operator from backscatter. When assessing risk in these situations it may be helpful to evaluate the Total Effective Dose Equivalent (TEDE) to the Public data (2c). In these tests the dosimeter (the "public") was not protected by the backscatter shield and exposure to radiation was still within standards. Clinical users must always use discretion and may elect to wear a leaded apron (or equivalent) if frequent use of the NOMAD Pro™ in unprotected positions behind the back scatter shield are expected. This should not be the case if operators receive adequate training and optimize patient positioning techniques; thus routine use of a leaded apron for users is not recommended.

5. Additional information:

- a. All annual exposure calculations assumed 15,000 exposures/year (high-volume practice of 300 exposures/wk). The NOMAD Pro™ would not be expected to be used for this many exposures. b. All 15,000 exposures would not be expected to be made by the same technician in a high-volume practice.
- c. All test exposures were at 0.99 seconds. Actual exposure times are typically much less than this.

REFERENCES

- 1. Air Force Instruction 48-125. USAF Personnel Dosimetry Program. 1 Mar 1999: 10-20.
- 2. Air Force Instruction 48-148. Ionizing Radiation Protection. 12 Oct 2001: 14-22, 30-31, 42-43.
- 3. U.S. Nuclear Regulatory Commission, Regulatory Guide 8.29. Office of Nuclear Regulatory Research. Revision 1, February 1996; 7–14.
- 4. Radiation Protection in Dentistry. NCRP Report No. 145. National Council on Radiation Protection and Measurements, Report No. 145. 31 Dec 2003; 8–12, 16–22, 27–30, 68–73, 76–77.

NOMAD Pro™ GUIDELINES FOR USE

- 1. The NOMAD Pro[™] should be secured when not in use.
- 2. All users should receive initial training from the Dental Radiology Officer or designee on proper use of the NOMAD Pro™. At a minimum, training should include radiation safety, operation of the NOMAD Pro™, and proper patient/provider positioning to ensure maximal benefit from the backscatter shield. Excellent instructional materials are now provided with the NOMAD Pro™
- 3. No unnecessary personnel should be allowed in the room when exposures are made.
- 4. Personnel must not be in the direct path of the NOMAD Pro™ x-ray beam.
- 5. As with any medical equipment item, the Medical Equipment Repair Center (MERC) must perform an initial evaluation of the NOMAD Pro™.
- 6. The MERC should return the NOMAD Pro[™] to Aribex[™] for evaluation and recertification every two years (earlier for heavy use). If damage is suspected the NOMAD Pro[™] should be returned immediately. The recertification tests include: kVp accuracy, kVp reproducibility, mA accuracy, timer accuracy, timer reproducibility, linearity, half-value layer, and radiation leakage tests.
- 7. NOMAD Pro[™] convenience and versatility does not justify it becoming a total substitute for traditional x-ray units already on location.